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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,874	09/30/2003	Howard Bernstein	17976-0006	6790

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EXAMINER	
GEORGE, KONATA M	

ART UNIT	PAPER NUMBER
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/675,874	BERNSTEIN ET AL.	
	Examiner	Art Unit	
	KONATA M. GEORGE	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12 and 14-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-10,12,14-30 and 33-56* is/are allowed.

6)☒ Claim(s) *11,31 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-12 and 14-56 are pending in this application.

Action Summary

The rejection of claim 11 under 35 U.S.C. 112, second paragraph as being indefinite is being maintained for the reasons stated in the office action dated July 27, 2007.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants in the claims recite the phrase “derivatives”. Webster’s Dictionary defines a derivative as “a substance derived from, or of such composition and properties, that it may be considered as derived from, another substance by chemical change, esp. by the substitution of one or more elements or radicals”. Based on this definition it is unclear what the derivative is.

Response to Arguments

Applicant's arguments filed December 13, 2007 have been fully considered but they are not persuasive.

Applicant argues that the phrase “derivatives” is defined in the specification. It is the position of the examiner that although derivatives are described in the specification it is not clear by way of the claims which of these derivatives is preferred. Furthermore, it is the position of the examiner that the phrase "derivatives" is vague and can encompass other compounds that are not described in the specification.

The rejection of claims 1-12, 14-30 and 33-56 under 35 U.S.C. 103(a) as being unpatentable over DeLuca et al. in view of Straub et al. is hereby withdrawn in view of applicants’ amendment to the claims.

The rejection of claims 31 and 32 under 35 U.S.C. 103(a) as being unpatentable over DeLuca et al. in view of Straub et al. is being maintained for the reasons stated in the office action dated July 27, 2007.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeLuca et al. (US 4,818,542) in view of Staub et al. (US 6,395,300).

Applicants claim a sustained release formulation comprising porous microparticles, which comprise a pharmaceutical agent and a hydrophobic matrix, wherein the microparticles have a geometric size of 0.1 to 5 microns and an average porosity of between 15% and 90% by volume.

Determination of the scope and content of the prior art
(MPEP §2141.01)

DeLuca et al. teach porous microspheres for the controlled delivery of drugs or other matrix confined materials (col. 2, lines 51-54). Column 3, line 65 through column 4, line 36 teach that the porous microspheres are derived from copolymeric and homopolymeric polyesters such as, polyglycolic acid, polylactic acid, and copolymers of glycolide and L-lactide. Column 5, line 65 through column 6, line 1 teach that the microspheres can have a particles size of from between about 1 to 150 microns, but preferably between about 0.5 to 50 microns. Column 6, lines 2-31 teach that the agents are incorporated into the pores of the microparticles and that “agent” refers to and diagnostic or pharmacologically active agent, which would be generally suited for introduction into a human. Column 6, line 39 teaches that excipients can be incorporated in the formulation. Column 6, lines 48-52 teach that the composition is suitable for inhalation and by administering through the mucous membrane of the nose, throat or bronchiopulmonary tissue. Column 6, lines 58-62 teach that additional active agents can be incorporated in the drug delivery system.

***Ascertainment of the difference between the prior art and the claims* (MPEP §2141.02)**

DeLuca et al. do not teach the agent being released from the microparticles in the lungs for at least 2 hours as claimed or the average porosity volume of 5% to 90% by volume. DeLuca et al. do not teach the formulation comprising a bulking agent. It is for this that Straub et al. is joined.

Straub et al. disclose a porous drug matrix additionally comprising water-soluble polymers or sugars, wetting agents such as surfactants, etc. and the matrix having a diameter size of about 100 nm to 5 microns (col. 3, lines 46-61). Column 4, line 11 through column 8, line 9 list the types of drugs that can be employed in the drug matrix. Column 8, lines 34-67 teach examples of the polymers and sugars that can be used in the matrix such as poylvinylpyrrolidone (line 41), xylitol (line 59) and lactose (line 63).

Finding of prima facie obviousness
***Rational and Motivation* (MPEP §2142-2143)**

Although the prior art reference of DeLuca et al. do not teach the agent being released from the microparticles in the lungs for at least 2 hours as claimed by applicant, it is the position of the examiner that this limitation would be met as DeLuca et al. teach the claimed invention. This limitation is considered functional language, therefore, if the composition of the prior art teach the composition of the instant invention, the function of the composition will also be the same. Furthermore, the composition as claimed is directed toward porous microparticles comprising a pharmaceutical agent and a matrix material. Since there is no additional information in

the specification with regards to the release profile (i.e. coating or physical makeup which makes it a sustained release), any porous microparticle having the claimed drug and matrix material would have the release profile as claimed. The determination of the average porosity volume would have been obvious to one of ordinary skill in the art. One of ordinary skill in the art when formulating a porous particle for the sustained release of a drug would have determined that the amount of pores on the particles would have an effect on the delivery of the drug; the more pores the greater the delivery of the drug over a period of time; the less amount of pores, the less delivery of the drug over the same period of time.

Straub et al. is relied upon to teach that excipients such as bulking agents can be added to the composition of DeLuca et al. (col. 8, lines 10-12 and 59-63). Therefore, when looking for examples of excipients that can be used in porous microparticles, one of ordinary skill in the art is taught to look to Straub et al. which teach a porous microparticle composition.

Response to Arguments

Applicant's arguments filed December 13, 2007 have been fully considered but they are not persuasive.

Applicant argues that DeLuca et al. do not teach that the pharmaceutical agent is dispersed and encapsulated within the hydrophobic matrix material. The examiner agrees, however, that limitation is not found in claims 31 and 32. It is therefore, the

position of the examiner that as the claims are written DeLuca et al. in view of Straub et al. teach the claimed invention and is thus obvious.

Allowable Subject Matter

Claims 1-10, 12, 14-30 and 34-56 are allowed. Applicants claim a sustained release formulation comprising porous microparticles, which comprise a pharmaceutical agent and a hydrophobic matrix, wherein the microparticles have a geometric size of 0.1 to 5 microns and an average porosity of between 15% and 90% by volume, wherein the pharmaceutical agent is dispersed and encapsulated within the hydrophobic matrix material. The closest prior art reference of DeLuca et al. disclose a porous microparticles, wherein the active agent is deposited in the pores of the polymer particles. It is not taught by the reference to encapsulate and disperse the agent within the hydrophobic matrix material.

Conclusion

Claims 11, 31 and 32 remain rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Telephone Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is 571-272-0613. The examiner can normally be reached from 8:00AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter, can be reached at 571-272-0646. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have question on access to the Private Pair system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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